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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,078	02/06/2004	Lukas Eisermann	31132.122	7137
46333 7590 11/27/2007 HAYNES AND BOONE, LLP 901 Main Street Suite 3100 Dallas, TX 75202			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 11/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

EP

Office Action Summary	Application No. 10/774,078	Applicant(s) EISERMANN ET AL.	
	Examiner James L. Swiger	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/6/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20 and 36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. 9US Patent 6,949,105).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bryan et al. discloses the claimed apparatus (see Figures 71, 39 and 39) that is provided by the method claim including the alignment instrument engaging the anchoring device with the body, driving an anchoring device (as shown in Fig. 39a) and providing the implantation device via a clamp (534). The device as shown by Bryan et al. is inherently capable of performing the actions as required by the claims and meets

the claim limitations. It is noted that the burring tool as shown in the full figure 71 may be replaced with an anchoring tool as shown in 39a, and the device would then provide the step of fixation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keller (US Patent 5,122,130) and Reese (US Patent 4,903,692) and Kambin (US Patent 5,395,317). Keller et al. disclose a device that inherently performs the claimed method to align vertebrae including the steps of aligning the vertebral instrument with a vertebral body (Fig. 1 and Fig. 10) and providing an instrument with an anchoring device (see figs. 2-3), and is able to align vertebrae (see Col. 3 in preparation for prosthesis (3) implantation via an implant engaging portion.

Keller disclose the claimed invention except for a separate anchoring device that is provided and performs the step of being aligned relative to an intervertebral space. Reese discloses a device that provides an anchor (58) via an implantation device (24) that is handled externally and capable of being connected and used with another device. The device is inherently capable of providing an anchor to an intervertebral area and may be offset from this intervertebral area when providing an anchor.

The combination of Keller and Reese disclose the claimed invention except for a clamp assembly that operatively connects these two devices, creating, essentially, a prosthetic insertion device that has a guide tool (aka, the anchor insertion device) and wherein both are held relative to one another via the clamp of Kambin (70). Though Kambin discloses the use of a guidewire, Kambin teaches the concept of using a clamping device (which would also be capable of a sliding engagement) to hold the two main portions of the alignment device relative to one another to perform the method as disclosed by the instant application

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device and perform the method as provided by Keller and modified by Reese and Kambin, effectively producing an prosthetic delivery device with an alignment tool, to have improved access to the appropriate spinal area during surgery.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keller and Reese and Kambin as applied to claim 20 above, and further in view of Houfburg (US Patent 6,283,966). The combination of combination of Keller and Reese and Kambin disclose the above method except for specifically an instrument comprising a radiographic marker. Houfberg discloses the use of a radiographic marker so that the instrument can be used by a surgeon in combination with the appropriate electromagnetic radiation system (MRI, CT) see (Col. 8, lines 4-53). It would have been obvious to one having ordinary skill in the art at the time the invention was a made to

perform the method of the combination of Keller and Reese and Kambin having at least a radiographic marker in view of Houfburg to better view the device during a surgical procedure.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keller and Reese and Kambin as applied to claim 20 above, and further in view of Leone, Jr. (US Patent 6,302,890). The combination of Keller and Reese and Kambin disclose the claimed method except for a device having a bubble level. Leone, Jr. disclose an alignment assembly having at least a bubble level. Leone, Jr. disclose a bubble level to aid in aligning the device (see Col. 3, lines 49-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of the combination of Keller and Reese and Kambin having at least a bubble level in view of Leone, Jr. to better align the device in use.

Claims 23-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keller and Reese and Kambin as applied to claim 20 above, and further in view of Warner et al. (US Patent 5,643,286). The combination of Keller and Reese and Kambin disclose the claimed method except for at least two clamps that, respectively, are operatively connected to the alignment device and comprise the step of slidably moving along the alignment device to better position the prosthetic device adjacent to the intervertebral space. Warner et al. disclose at least two clamps (42 and 32) that are able to attach to an alignment device, or even a prosthesis holder that could be attached via an 'instrument holding member' and are able to be moved relative, respectively, to one another for adjusting the implantation device (see Col. 4, lines 16-

47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Keller and Reese and Kambin having at least two clamps that can move the prosthesis holder and alignment device relative to one another in view of Warner et al. to better guide the device.

Response to Arguments

In further consideration of the previous interpretation and the telephone interview held on 9/25/2007, previous rejections have been withdrawn, however claims are still found to be unpatentable in view of the above rejections. Thus, the previous arguments dated 9/21/2007 have been rendered moot.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

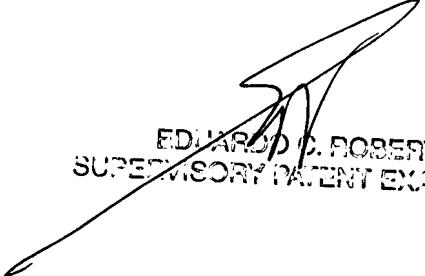
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLS

 11/26/07


EDWARD C. ROBERT
SUPERVISORY PATENT EXAMINER